JUL 18 2002 K021326

BIOMÉRIEUX

510(k) SUMMARY

Submitter's Name:	Kelly J. Rowland
Title:	Regulatory Affairs Specialist
Applicant Name:	bioMerieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Kelly J. Rowland
Phone Number:	(314) 731-8386
Fax Number:	(314) 731-8689
Date of Preparation:	1 April 2002
Device Trade/Proprietary Name:	VIDAS Testosterone (TES) Assay
Device Common/Usual Name:	Enzyme-linked Fluorescent Immunoassay (ELFA) for the quantitative detection of total testosterone.
Classification Name:	Radioimmunoassay, Testosterones and Dihydrotestosterone, 21 CFR §862.1680
Predicate Device Trade Name:	Diagnostic Products Corporation Coat-A-Count® Total Testosterone (K813401) CIBA Corning ACS Testosterone Immunoassay (K934562) (CIBA now known as Chiron)

Device Description:

The VIDAS Testosterone (TES) Assay is an enzyme-linked fluorescent immunoassay (ELFA) performed in an automated VIDAS instrument. All assay steps and assay temperatures are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as the solid phase as well as a pipettor for the assay. Reagents for the assay are in the sealed TES Reagent Strips.

The sample is taken and transferred into the well containing the conjugate, which is an alkaline phosphatase-labeled testosterone derivative. The testosterone present in the serum and the testosterone derivative in the conjugate compete for the anti-testosterone specific antibody sites coated to the inner surface of the SPR. Unbound components are eliminated during the washing steps.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-embelliferone), the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is inversely proportional to the concentration of testosterone present in the sample.

At the end of the assay, results are automatically calculated by VIDAS in relation to the calibration curved stored in memory, and then printed out.

Intended Use:

VIDAS Testosterone is an automated test for use on the VIDAS analyzer for the enzyme immunoassay measure of total testosterone in human serum or plasma (heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay).

Technological Characteristic Summary:

Major Similarities:
1. Both are quantitative tests that measure Testosterone levels.
2. Both tests are carried out with automated systems.

Major Differences:
1. Coat-A-Count is a solid-phase radioimmunoassay with a gamma counter detector. VIDAS TES is an enzyme immunoassay sandwich method with a final fluorescence detection carried out in the VIDAS instrument.
2. Coat-A-Count antibody capture is carried out on the sample in the polypropylene tube, which is then decanted for detection. The SPR serves as the solid phase as well as the pipetting device for VIDAS TES.
3. Coat-A-Count requires a 3-hour specimen incubation time. VIDAS TES samples do not need incubation before detection.
4. The Coat-A-Count requires multiple calibrators that must be used with every run. VIDAS TES has one calibrator included in each kit that may be run every 14 days.
5. Specimens that may be used with the Coat-A-Count assay include urine, serum or plasma. VIDAS TES specimens must be serum or plasma.

Performance Data:

Non-clinical Testing

<table>
<tr><th></th><th>VIDAS TES Assay</th><th>COAT-A-COUNT Assay</th></tr>
<tr><td>Specificity</td><td>
<table>
<tr><th>Tested Compound</th><th>Cross-Reactivity %</th></tr>
<tr><td>Testosterone</td><td>100.00</td></tr>
<tr><td>19-Nortestosterone</td><td>6.4</td></tr>
<tr><td>5α-dihydrotestosterone</td><td>0.98</td></tr>
<tr><td>Δ4-androstenedione</td><td>0.07</td></tr>
<tr><td>5α-androstane-3α, 17β-diol</td><td>0.14</td></tr>
<tr><td>5-androstene-3β, 17β-diol</td><td>0.02</td></tr>
<tr><td>11β-hydroxytestosterone</td><td>0.85</td></tr>
<tr><td>Deoxycorticosterone</td><td>< 0.01</td></tr>
<tr><td>Corticosterone</td><td>< 0.01</td></tr>
<tr><td>Progesterone</td><td>< 0.01</td></tr>
<tr><td>sDHA (sulfate dehydroepiandrosterone)</td><td>< 0.01</td></tr>
<tr><td>Estradiol</td><td>< 0.01</td></tr>
<tr><td>Estriol</td><td>< 0.01</td></tr>
<tr><td>Estrone</td><td>< 0.01</td></tr>
</table>
</td><td>Specificity depicted as a table located in the device package insert</td></tr>
<tr><td>Limit of Detection</td><td>0.1 – 1.3 ng/mL</td><td>4 ng/dL (0.14 nmol/L)</td></tr>
<tr><td>Expected Value for healthy males/females</td><td>Women 0.1 – 0.9 ng/mL
Men 3.0 – 10.6 ng/mL</td><td>
<table>
<tr><th>87 male serum
81 female serum</th><th>n</th><th>Median (ng/dL)</th><th>Central 95% Range</th><th>Absolute Range</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Females</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Ovulating</td><td>41</td><td>24</td><td>22 – 80</td><td>20 – 81</td></tr>
<tr><td>Oral contraceptive</td><td>13</td><td>15</td><td>---</td><td>10 – 28</td></tr>
<tr><td>Postmenopausal</td><td>27</td><td>20</td><td>4.0 – 62</td><td>4.2 – 74</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Males</td><td></td><td></td><td></td><td></td></tr>
<tr><td>20 – 49 years</td><td>68</td><td>630</td><td>262 – 1,593</td><td>245 – 1,836</td></tr>
<tr><td>=> 50 years</td><td>19</td><td>427</td><td>181 – 758</td><td>181 - 772</td></tr>
</table>
</td></tr>
</table>

Non-clinical Testing (Continued)

	VIDAS TES Assay	COAT-A-COUNT Assay
Interference	**EDTA:** The presence of EDTA leads to an increased concentration value of testosterone. Plasma collected on EDTA must not be used with the VIDAS TES Assay (also noted in package insert). **Heparin:** No known interferences from samples collected on heparin. **Others:** Hemolysis, lipemia, and bilirubinemia (after spiking samples) were found not to significantly influence this assay. However, it is recommended that clearly hemolyzed, lipemic, or icteric samples not be used and, if possible, to collect a new sample.	Identified as Specificity on package insert. Crossreactivity with dihydrotestosterone is less than 5%. Llipemia, bilirubin nor hemolysis interferes with the assay. Heparinized plasma yields essentially the same values as serum.
Intra-Run Precision CV%	2.73 – 7.60 CV% (VIDAS) 1.71 – 10.48 CV% (mini VIDAS) 5.67 – 10.48 CV% (Assay/Kit)	Depicted as graph located on device package insert
Inter-Run Precision CV% (Reproducibility or Total Precision)	5.80 – 11.93 CV% (VIDAS) 2.64 – 11.34 CV% (mini VIDAS) 10.72 – 11.3 CV% (Assay/Kit)	5.9 – 12 CV%
Dilution Study (3 sera collected from male patients were diluted in a serum collected from a female patient (0.26 ng/mL)	78.4 – 100.0%	Located on device package insert
Recovery Test (3 plasma samples spiked with known quantities of testosterone)	89.9 – 115.2%	Depicted as table located on device package insert

Correlation: A comparison of testosterone values from 216 samples run with both VIDAS TES and DPC Coat-A-Count demonstrated good agreement with the following statistical data: slope of 1.0602, ordinate of –0.137 and a correlation coefficient of 0.9660.

Recovery: Linearity studies performed by sampling plasma samples spiked with known quantities of testosterone and tested singly in 3 series. The average mean recovery was 100.1% with individual mean recoveries ranging from 89.9% to 115.2%.

Precision: Intra-assay precision ranged from 2.73 CV% to 7.60 CV%. Total precision ranged from 5.80 CV% to 11.93 CV%

Specificity: There was no significant interference from compounds similar to testosterone. In addition, there was no significant interference from potential sample contaminants such as Heparin, Bilirubin, Hemoglobin, and Triglycerides (lipids). However, the presence of EDTA leads to an increased concentration value of testosterone. Plasma collected on EDTA must not be used with the VIDAS TES Assay (also noted in package insert).

Limit of Detection: The limit of detection is set at 0.1 ng/mL

Clinical Testing

One hundred eighty-three serum samples were assayed in parallel using VIDAS TES and TESTO CT2 and subjected to linear regression analysis. Good correlation between the two methods as the data gave an $R^2 = 0.8106$ value.

In addition, thirteen sera assayed using the reference method (ID-GCMS) were also assayed in two different series using the VIDAS TESTOSTERONE kit and in duplicate using TESTO CT2 kit.

The results were compared using regression analysis. Both methods gave very good correlation.

Comparison of Mass Spectrometry and VIDAS TES
y (VIDAS TES) = 0.944 X (ID-GCMS) + 0.1452
$R^2 = 0.8989$
R = 0.94

Comparison of Mass Spectrometry and Testo CT2
y (Testo CT2) = 0.8884 X (ID-GCMS) + 0.3664
$R^2 = 0.9649$
R = 0.98

Conclusion

Overall, the VIDAS Testosterone (TES) Assay give very similar results to those obtained with the expert tested kit (TESTO CT2 Kit - Cis Bio International).

The VIDAS Testosterone (TES) Assay give reproducible results, which correlate, closely with the results obtained using the reference method (ID-GCMS). It matches the analytical quality criteria required in the medical laboratory and it give results which are entirely consistent with the clinical picture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 18 2002

Ms. Kelly J. Roland
Specialist, Regulatory Affairs
bioMerieux, Inc.
595 Anglum Road
Hazelwood, MO 63042-2320

Re: k021326
Trade/Device Name: VIDAS Testosterone (TES) Assay
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class II;
Product Code: CDZ, JIS, JJX
Dated: April 23, 2002
Received: April 26, 2002

Dear Ms. Roland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K021326

Device Name: VIDAS Testosterone (TES) Assay

Indications for Use:

VIDAS Testosterone is an automated test for use on the VIDAS analyzer for the enzyme immunoassay measure of total testosterone in human serum or plasma (heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended as an aid in the disgnosis and management of conditions involving excess or deficiency of this androgen.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021326

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ✓

Concurrence of CDRH, Office of Device Evaluation (ODE) Per 21 CFR 801.109)